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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,970	08/04/2003	Satishchandra P. Patel	M0025.0293/P0293	4466

7590 04/16/2007  
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New York, NY 10036-2714

EXAMINER
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TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/16/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/632,970

Applicant(s)

PATEL, SATISHCHANDRA P.

Examiner

Susan T. Tran

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulye WO 00/33862 (Mulye '862).

Mulye teaches a self-emulsifying composition comprising 0.01-50% cyclosporine, nonionic surfactant having HLB greater than 10, and mixture of fatty acids such as propylene glycol ester having at least about 60% by weight monoesters based on the total weight of the propylene glycol ester (abstract; page 14; pages 16, lines 28 through page 17, lines 1-9; and page 20). The composition is suitable for drinking solution, and hard/soft gelatin capsule formulations (page 23, lines 21 through page 24, lines 1-6). The composition further comprises antioxidants such as tocopherol, BHA, BHT, and the like (page 21, lines 20-27).

Mulye does not explicitly teach mixture of mono- and diester propylene glycol. However, Mulye teaches mixture of propylene glycol maybe use. Thus, it would have been obvious to one of ordinary skill in the art to include diester propylene glycol in the mixture, because Mulye does not exclude the use of diester propylene glycol, because Mulye teaches mixture of fatty acids contain 60% of monoester propylene glycol (page 16), and because Mulye only exclude the present of triglycerides.

### ***Response to Arguments***

Applicant's arguments filed 01/19/07 have been fully considered but they are not persuasive.

Applicant argues that "*Mulye teaches one skilled in the art that a propylene glycol ester of a 6 to 18 carbon atom fatty acid in which the monoester is at least 60% and the diester is no greater than 40% should be used. The composition of the present invention in differs from this reference in two respects, namely that the fatty acid have from 8 to 10 carbon atoms and the monoester is less than 60 mole percent of the monoester/diester mixture. As the Examiner has pointed out, one skilled in the art would not believe such a composition was storage stable. The Applicant surprisingly found that when the fatty acid had 8 to 10 carbon atoms and the monoester was less than 60 mole percent rather than greater than 60% by weight, the composition was storage stable. This result is clearly unobvious*".

However, contrary to the applicant's argument, Mulye '862 clearly teaches that the composition of Mulye provides excellent storage stability (see page 26, first paragraph). The withdrawn 112, first paragraph rejection using a different Mulye reference (US 6,436,430), which teaches different subject matter than the cited Mulye '862 under the 103(a) rejection. Applicant's attention is called to page 15, lines 2-4, Mulye '862 teaches the propylene glycol esters of C<sub>6</sub>-C<sub>18</sub> fatty acids having monoester equal to about 60% by weight, based on the total weight of the propylene glycol ester. This teaching is clearly obvious over claim 1 and dependent claim 2. To address applicant's second concern, applicant's attention is called again, to page 15, lines 29-

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30, Mulye teaches propylene glycol ester contains, preferably, 8-10 carbon atoms, as required by the present invention. Accordingly, the 103(a) rejection over Mulye '862 is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

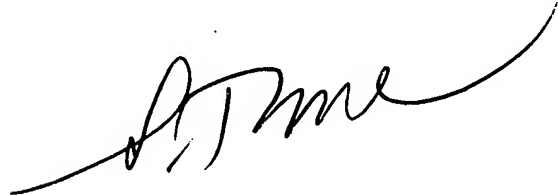
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', is written over a horizontal line.

S. Tran  
Primary Examiner  
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